



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAR 24 1999

4449 '99 APR -7 A9:53

Mr. John P. Venardos  
Vice President, Regulatory Affairs  
International Product Management  
Herbalife International of America, Inc.  
9800 La Cienega Boulevard  
P.O. Box 80210  
Inglewood, California 90301

Dear Mr. Venardos:

This is in response to your letter of December 30, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission, responding to FDA's letter of August 18, 1998, asked that FDA provide you the basis upon which it had determined that menopause was a "disease."

FDA does not believe that menopause itself is a disease. The agency's tentative conclusions on this subject are set forth in its proposed rule entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body" which was published in the April 29, 1998 Federal Register (63 FR 23624). The proposal explained that "certain natural states, such as pregnancy, aging, or the menstrual cycle, that are themselves not 'diseases,' are sometimes associated with abnormalities that are characterized by a specific set of signs or symptoms, and thus meet the definition of disease" (see 63 FR 23627). The proposal further stated that "a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body, such as toxemia of pregnancy, premenstrual syndrome, or abnormalities associated with aging such as presbyopia, decreased sexual function, Alzheimer's disease, or hot flashes. Claims that did not refer to a recognizable abnormality resulting from a natural state or to its signs or symptoms...would not be disease claims..."

The proposed rule has not been finalized. In the context of the rulemaking, FDA is actively considering which claims should and should not be considered disease claims. Therefore, our current view about what claims are permitted under 21 U.S.C. 343(r)(6) may change as we develop a final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The issue you raised in your letter will be addressed by the agency in its consideration of comments received in response to the proposed rule and development of a final rule.

978-0163

LET 263

Page 2 - Mr. John P. Venardos

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file, OSN#63094)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:1/11/99

revised per GCF-1:LNickerson:3/23/99

f/t:rjm:HFS-456:3/23/99:63094.adv:disc36



63094

HERBALIFE INTERNATIONAL OF AMERICA, INC.  
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(310) 410-9600 • FAX: (310) 258-7124

JOHN P. VENARDOS  
Vice President, Regulatory Affairs  
International Product Management

December 30, 1998

11/5/98

Office of Special Nutritionals (HFS-450)  
Center For Food Safety and Applied Nutrition  
**FOOD & DRUG ADMINISTRATION**  
200 C Street, S.W.  
Washington, D.C. 20204

Ref.: **Woman's Choice Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. is commercializing Woman's Choice dietary supplement in the United States. This letter is intended to replace our August 4, 1998 notification letter to the FDA advising the agency of statements being made for the Woman's Choice product. It contains a revision of certain statements made in our August 4 notification letter, and reflects the Company's response to the FDA's comments on those statements, as set forth by the agency in its August 18, 1998 "courtesy" letter to us.

With all due respect, Herbalife disagrees with the view expressed in the agency's August 18 letter, which characterized the naturally-occurring process of menopause as a "disease". We respectfully request that the agency share with us the scientific basis supporting such an opinion, an opinion which we believe runs directly counter to the prevalent view of medical experts - which is that menopause is a natural condition which occurs as women age. Despite our disagreement with the agency's views on this subject, Herbalife has nonetheless revised the language that it will use to promote Woman's Choice in our product literature.

Woman's Choice dietary supplement is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

**LABEL**

Suggested Serving: One or two tablets per day.

Woman's Choice contains a special blend of isoflavones from Red Clover, Soy and Kudzu plus Black Cohosh which helps promote hormone balance in women.

**PRODUCT LITERATURE**

As women approach age 35 and beyond, they experience a variety of indications, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during time of life. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover Extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

Also see dockets 975-0163 + 0162

Office of Special Nutritionals (HFS-450)  
Center For Food Safety and Applied Nutrition  
**FOOD & DRUG ADMINISTRATION**  
December 30, 1998  
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- Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance.

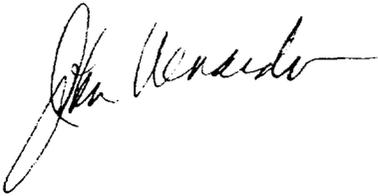
Product labeling prominently bears the required boxed statement, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Finally, we look forward to receiving at your earliest convenience the information requested above that supports the agency's view, stated in the August 18 letter, that menopause is somehow a disease rather than a naturally-occurring process.

Please do not hesitate to advise should you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John Wensel", written in a cursive style.

**File: Woman's Choice Dietary Supplement**



Suggested Serving: One or two tablets per day.

Woman's Choice contains a special blend of isoflavones from Red Clover, Soy and Kudzu plus Black Cohosh which helps promote hormone balance in women.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Herbalife products are available only through Herbalife Independent Distributors.

301345-00  
© 1998 HERBALIFE INTERNATIONAL, INC., U.S.A.



# Woman's Choice

Dietary Supplement for Women

30 TABLETS

EACH TABLET PROVIDES:

RED CLOVER EXTRACT (1%)	50 MG
SOY ISOFLAVONES EXTRACT (40%)	30 MG
KUDZU EXTRACT (40%)	30 MG
BLACK COHOSH EXTRACT (8%)	10 MG
BIO-ABSORPTION COMPLEX-5	23 MG
LECITHIN, ASCORBYL PALMITATE, PLANT CELLULOSE ENZYME, CINNAMON POWDER AND BIOPERINE® (BLACK PEPPER EXTRACT).	

30-day money back guarantee.

FORMULATED EXCLUSIVELY FOR:  
HERBALIFE INTERNATIONAL OF AMERICA, INC.  
LOS ANGELES, CA 90080-0210, U.S.A.

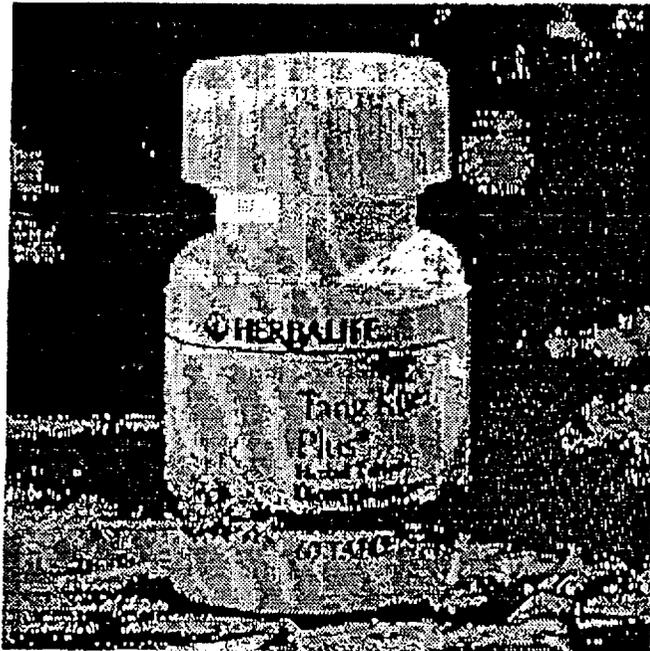
MADE IN U.S.A.

City  $\gamma < 100$  71

40%



## Special Supplements For Women



### Tang Kuei Plus\*

Superior nutritional tonic especially for women.

Tang Kuei has been used for centuries in China as a general nutritional tonic, particularly beneficial for women. The root of the plant is preferred because it is a rich source of B vitamins, Calcium, Iron, Magnesium and essential oils. In the Chinese system, Tang Kuei is considered a "superior herb" that can be taken on a daily basis and is often added to soups and broths to increase the nutritional value of these dishes.

- Specially formulated to normalize the challenges associated with a woman's menstrual cycle.
- Includes the additional benefit of Chamomile. This multipurpose plant was used by the Ancient Greeks and was considered a sacred herb by the early Anglo-Saxons.
- Includes Calcium and Magnesium, as well as Vitamin A.

#1014 (case of 12)

#0003 (HAP or unit) \$12.50

### Woman's Choice

Dietary supplement for women.

As women approach age 35 and beyond, they experience a variety of indications, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during this time of life. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

- o Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance.

#3015 (case of 12)

#0166 (HAP or unit) \$22.90

